

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0330]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for electronically submitting notices of intent to slaughter for human food purposes.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD

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Display Date 8-6-03

Publication Date 8-7-03

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the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes—21 CFR Part 511 (OMB Control Number 0910-0450)—Extension

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) gives FDA the authority to issue regulations setting out the conditions for marketing animals treated with investigational new animal drugs for food use. Under this authority, FDA's regulations at § 511.1(b)(4) (21 CFR 511.1(b)(4)), provide that sponsors must obtain authorization to slaughter these animals for food. The Center for Veterinary Medicine (CVM) may grant such authorization to a sponsor under § 511.1(b)(5). If CVM authorizes the slaughter of investigational animals for food use, CVM issues a slaughter authorization letter to new animal drug sponsors which sets the terms under which such animals treated with investigational new animal drugs may be slaughtered. The authorization letter states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless CVM waives this notice in the authorization letter. Currently, slaughter notices are submitted to CVM on paper. This guidance will give sponsors the option to submit a slaughter notice electronically as an e-mail attachment. The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions. The likely respondents to this collection of information are new animal drug sponsors who have conducted clinical studies under § 511.1(b).

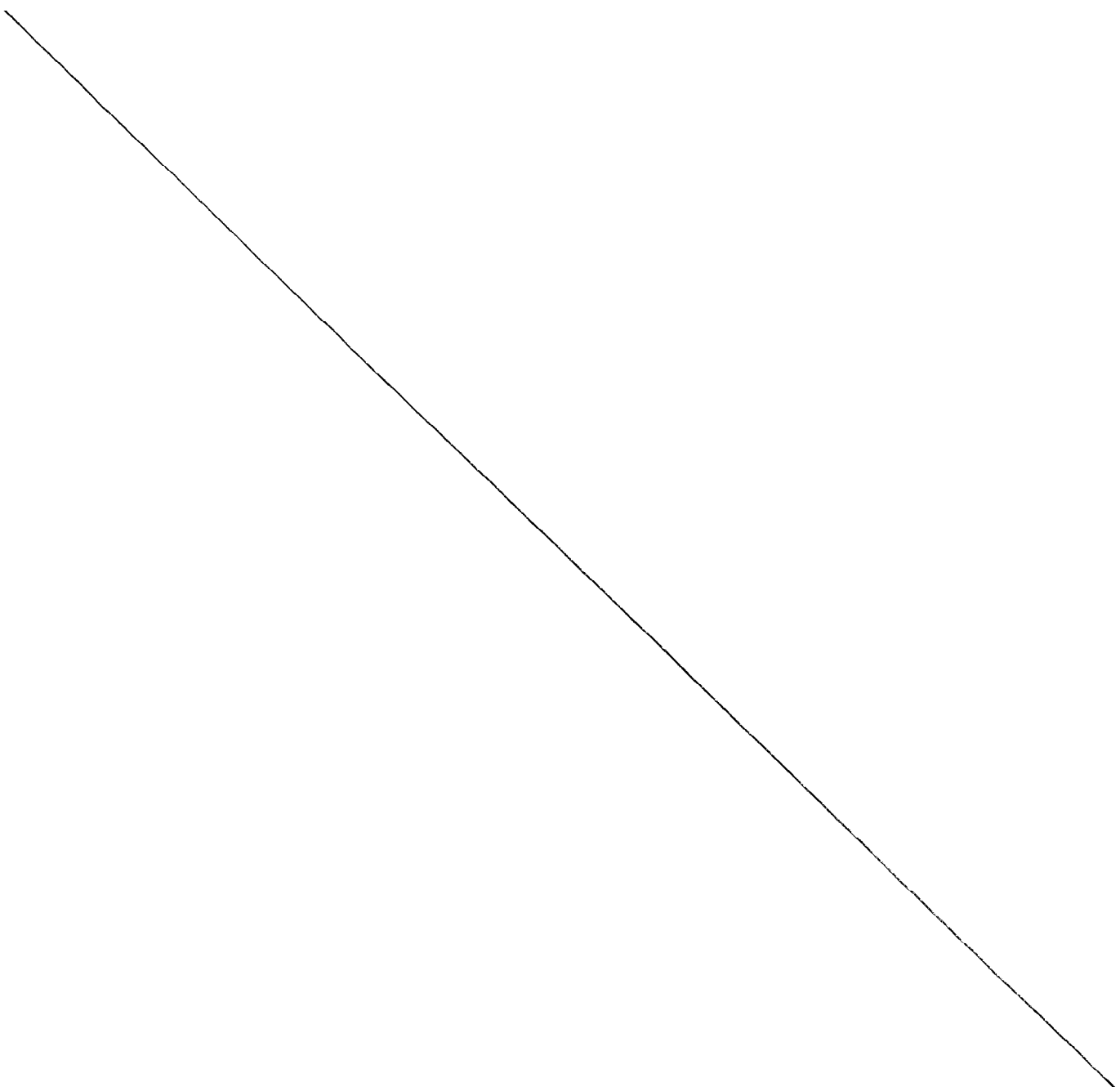
FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form No	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3488	12	7	84	0.40	33.6

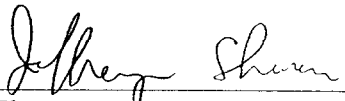
¹ There are no capital costs or operating and maintenance costs associated with this collection of information

Submitting a slaughter notice electronically represents a new medium for submission of information currently submitted on paper. The reporting burden for compilation and submission of this information on paper is included in OMB clearance of the information collection provisions of § 511.1 (OMB control number 0910–0117). The estimates in table 1 of this document reflect



the burden associated with putting the same information on FDA Form No. 3488 and resulted from discussions with sponsors about the time necessary to complete this form.

Dated: JUL 30 2003
July 30, 2003.

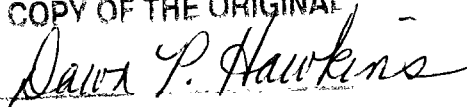


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Dawn P. Hawkins